

REMARKS

The forgoing amendments to the specification are made to insert the required SEQ ID NO identifiers associated with each listed sequence. Enclosed with this paper is a Substitute Sequence listing; and a statement attesting to the identity of the Substitute Sequence Listing with the Computer Readable Form of the Sequence Listing, also provided. In addition, a paragraph has been added to the specification identifying the prior applications to which benefit is entitled. No other amendments to the specification, i.e., trademarks, other sequences, etc., have been found necessary. The courtesy of the Examiner to point out any such is respectfully requested. The comment about the drawings and the listing of references in the specification is noted.

The Claims in the case are 31-46, corresponding to 1-3, 5, 8-9, 12-19, and 29-30. These claims had been elected. Applicants' attorney hereby affirms the election previously made, to the invention of group I; the species of Claim 5, now Claim 34, is also elected. The non-elected claims have been deleted. Applicants reserve the right to file additional applications claiming the subject matter of the deleted claims at some future date.

THE REJECTION UNDER 35 U.S.C. § 101

The Office Action has rejected claims 1-3, 5, 7-9 and 18 10 under 35 U.S.C. § 101, asserting that the claim does not distinguish the claimed yeast or fungus from a product of nature. In response, the new claims, adding the modifier "isolated" to the subject matter obviates the basis for the rejection. Reconsideration and withdrawal of this aspect of the rejection are respectfully requested.

The Office Action also has rejected the claims under 35 U.S.C. § 101, asserting that the claimed invention is not supported by a specific, substantial and credible utility or a well established utility. Applicants respectfully traverse the rejection.

The PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince the person of the invention's asserted utility. In re Brana, 51 F.3d 1560 (Fed. Cir. 1995).

The claimed invention is directed to specified isolated nucleic acid molecules. The specification discloses that the specified isolated nucleic acid molecules have been identified as critical for growth and cell division of *Candida albicans*, and therefore can be used as selective drug targets to treat *Candida albicans* infections. . See, e.g., Abstract. The specification discloses that the specified isolated nucleic acid can be employed as a selective target for drugs to treat infections caused by or associated with yeast and fungi or for the treatment of proliferative disorders or for the prevention of apoptosis in certain diseases. See Abstract.

The specification discloses that Applicants identified a range of specific nucleotide sequences which are involved in the molecular pathways eventually leading to cell death. These sequences and their homologues in other yeast and fungi as well as the polypeptides which they encode represent novel molecular targets which can be incorporated into an assay to selectively identify compounds capable of inhibiting or activating expression of such polypeptides.

Underexpression or overexpression of any component of a process (e.g. translation) could lead to altered sensitivity to an inhibitor of a relevant step in that process. Such an inhibitor should be more potent against a cell limited by a deficiency in the macromolecule catalyzing that step and/or less potent macromolecules, as compared to the wild type (WT) cell. The component which is present in altered form or amount in a cell whose growth is affected by a test compound is potentially the site of action of the test compound. Thus, the claimed invention meets the utility requirement of 35 U.S.C. § 101. Reconsideration and withdrawal of the rejection of claims 31-47 under 35 U.S.C. § 101 are respectfully requested.

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Office Action rejects the claims under 35 U.S.C. § 112, first paragraph, asserting that the application lacks enablement as well as a credible utility. Applicants respectfully traverse the rejection.

Applicants respectfully submit that (1) one skilled in the art would know how to use the isolated nucleic acid molecule and corresponding amino acid sequence claimed in the claims; and (2) the claimed invention is described in the invention so as to convey to one skilled in the art that Applicants had possession of the claimed invention, as well as to enable those practicing the invention to do so without unnecessary experimentation.

The Office Action cites *Wands* as support for the proposition that the specification enable those skilled in the art to carry out the invention without undue experimentation. The Examiner has particularly commented that in regard to fragments of molecules, those attempting to follow the teaching of the instant application would be forced to make and test any and all of the fragments within the claims. While Applicants agree with the Examiner as to the law, they respectfully disagree with the application of it to the specifics of the claimed invention. Applicants further assert that the instant specification does in fact offer sufficient guidance to those following the invention to complete it without any such excessive experimentation. Applicants submit that the specification provides ample guidance to those skilled in the art to use the claimed nucleic acid with a promoter to use the nucleotides of this invention to screen for compounds modulating the growth of the hostile organism, as well as to prepare pharmaceutical compositions containing such compounds. See the specification page 2, lines 18-20; page 16, lines 20-28; and page 17, lines 6-30.

Applicants submit that this disclosure coupled with what was known in the art at the time this application was filed provides sufficient guidance to one skilled in the art how to make and use the various aspects of the claimed invention.

Reconsideration and withdrawal of the rejection of claims 31-47 under 35 U.S.C. §112, first paragraph, are respectfully requested.

THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejects the claims under 35 U.S.C. § 112, second paragraph, asserting that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention.

Applicants respectfully submit that for the reasons provided, the claims are definite in that they particularly point out and distinctly claim that which Applicants regard as the invention. The claims corresponding to those rejected under 35 U.S.C. § 112, second paragraph have been amended to provide language which is allowable. See the Claims 33, 35, 38, 44, 45 and 46, which correspond to Claims 3, 8, 13, 19, 29 and 30. Reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 112, second paragraph, are respectfully requested.

Early consideration and prompt allowance of the pending claims is respectfully requested.

CONCLUSION

The Examiner is respectfully requested to reconsider and withdraw the rejections. Applicants submit the Application is now in condition for allowance and respectfully requests early notice to that effect.

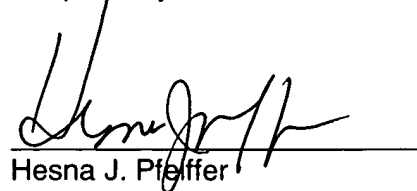
Should the Examiner feel that telephonic communication with Applicants' representative would further the prosecution of the instant application, he is invited to telephone the undersigned.

PETITION FOR EXTENSION OF TIME

Applicant(s) petition(s) the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated June 29, 2004 for three (3) months from September 29, 2004 to December 29, 2004.

Please charge Deposit Account No. 10-0750/ORT1430/LAD2 in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this page are included with this paper.

Respectfully submitted,



Hesna J. Pfeiffer
Attorney for Applicants
Reg. No. 22,640

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2830
1430amendment

Date: December 15, 2004

CONCLUSION

The Examiner is respectfully requested to reconsider and withdraw the rejections. Applicants submit the Application is now in condition for allowance and respectfully requests early notice to that effect.

Should the Examiner feel that telephonic communication with Applicants' representative would further the prosecution of the instant application, he is invited to telephone the undersigned.

PETITION FOR EXTENSION OF TIME

Applicant(s) petition(s) the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated June 29, 2004 for three (3) months from September 29, 2004 to December 29, 2004.

Please charge Deposit Account No. 10-0750/ORT1430/LAD2 in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this page are included with this paper.

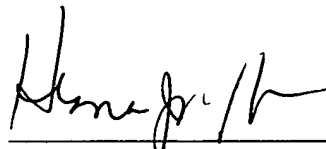
12/20/2004 FRETEK11 00000035 100750 09857372

01 FC:1253 1020.00 DA

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2830
1430amendment

Date: December 15, 2004

Respectfully submitted,



Hesna J. Pfeiffer
Attorney for Applicants
Reg. No. 22,640